REMARKS

Claims 1, 2, and 4-11 have been rejected. Claims 1 has been amended to indicate that the non-self IgE portion consists essentially of a CH2 domain of IgE and a CH4 domain of IgE, and claim 8 has been amended to depend from claim 2. In addition, claims 25-54 have been added herein. Thus, claims 1, 2, 4-11, and 25-54 are pending. The application as originally filed supports these amendments as well as new claims 25-54. For example, Figure 2 discloses polypeptides having a non-self IgE portion that consists essentially of a CH2 domain of IgE and a CH4 domain of IgE. Thus, no new matter has been added. In light of this amendment and following remarks, Applicant respectfully requests reconsideration and allowance of claims 1, 2, 4-11, and 25-54.

Rejections under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1, 2, and 4-11 under 35 U.S.C. §112, first paragraph, stating:

> [T]he specification, while being enabling for "An immunogenic polypeptide comprising a non-self IgE CH2 domain, a self IgE CH3 domain, and a nonself IgE CH4 domain" does not reasonably provide enablement for:
>
> A) "An immunogenic polypeptide comprising a self IgE portion and a nonself IgE portion, and wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE"(claim 1).
>
> B) "The immunogenic polypeptide of claim 1 wherein the nonself portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said nonself IgE portion," (claim 5).
>
> C) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH2 domain (claim 6).
>
> D) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH4 domain (claim 7).

Applicant respectfully disagrees and submits that the specification as filed not only enables an immunogenic polypeptide comprising a non-self IgE CH2 domain, a self IgE CH3 domain, and a non-self IgE CH4 domain as indicated by the Examiner but also enables the originally filed claims. To further prosecution, however, claim 1 has been amended herein to indicate that the non-self IgE portion consists essentially of a CH2 domain of IgE and a CH4

domain of IgE. In light of this amendment, Applicant respectfully requests withdrawal of the rejection of claims 1, 2, 4-7, and 11 under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §102(b)

The Examiner rejected claims 1, 2, 4-7, and 11 under 35 U.S.C. §102(b) as being anticipated by EP 0327378 for the reasons indicated in the Official Action mailed July 3, 2000. In addition, the Examiner stated that the EP 0327378 reference "teaches a construct comprising IgE including a CH3 domain from the same or different species, thus the reference anticipates the claim."

Applicant respectfully disagrees. Claim 1 recites an immunogenic polypeptide having (1) a self IgE portion that contains at least a portion of a CH3 domain of IgE and (2) a non-self IgE portion that consists essentially of a CH2 domain of IgE and a CH4 domain of IgE. At no point does the EP 0327378 reference disclose an immunogenic polypeptide having a self IgE portion in combination with a non-self IgE portion that consists essentially of a CH2 domain of IgE and a CH4 domain of IgE. In addition, the EP 0327378 reference fails to disclose a single immunogenic polypeptide that is effective to induce an anti-self IgE response in a mammal. In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 1, 2, 4-7, and 11 under 35 U.S.C. §102(b).

Rejections under 35 U.S.C. §103(a)

The Examiner rejected claims 1 and 8-9 under 35 U.S.C. §103(a) as being unpatentable over EP 0327378 for the reasons indicated in the Official Action mailed July 3, 2000. In addition, the Examiner indicated that "a product cannot be separated from its properties, therefore, the polypeptide of the reference has the immunogenic properties of the product of the instant claims."

Applicant respectfully disagrees. Proper analysis under §103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition, and (2) whether the prior art would also have revealed that in so making, those of ordinary skill would have had a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As set forth above, the

EP 0327378 reference does not disclose an immunogenic polypeptide having (1) a self IgE portion that contains a portion of at least a portion of a CH3 domain of IgE and (2) a non-self IgE portion that consists essentially of a CH2 domain of IgE and a CH4 domain of IgE. Further, at no point does the EP 0327378 reference suggest that one of ordinary skill in the art should make an immunogenic polypeptide as presently claimed. Moreover, the EP 0327378 reference fails to provide the required reasonable expectation of success in achieving an immunogenic polypeptide having (1) a self IgE portion that contains a portion of at least a portion of a CH3 domain of IgE and (2) a non-self IgE portion that consists essentially of a CH2 domain of IgE and a CH4 domain of IgE such that the immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal. Thus, the EP 0327378 reference does not render the presently claimed invention obvious. In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 1, 8, and 9 under 35 U.S.C. §103(a).

CONCLUSION

Applicant respectfully submits that claims 1, 2, 4-11, and 25-54 are in condition for allowance, which action is requested. Enclosed is a check for excess claim fees and the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Version with markings to show changes made

In the claims:

Claims 1 and 8 have been amended as follows:

1. (Amended Twice) An immunogenic polypeptide, comprising a self IgE portion and a non-self IgE portion, wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal, [and] wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE, and wherein said non-self IgE portion consists essentially of a CH2 domain of IgE and a CH4 domain of IgE.

8. (Amended Once) The immunogenic polypeptide of claim [1] 2, wherein said non-self IgE portion comprises an IgE sequence present in a non-placental mammal.

Please add new claims 25-54 as follows:

Claims 25-54 have been added as follows:

--25. An immunogenic polypeptide, comprising a self IgE portion and a non-self IgE portion, wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal, wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE, and wherein said immunogenic polypeptide lacks a CH1 domain of IgE.

26. The immunogenic polypeptide of claim 25, wherein said mammal is a human.

27. The immunogenic polypeptide of claim 26, wherein said non-self IgE portion comprises an IgE sequence present in a non-placental mammal.

28. The immunogenic polypeptide of claim 27, wherein said non-placental mammal is selected from the group consisting of opossum, platypus, koala, kangaroo, wallaby, and wombat.

29. The immunogenic polypeptide of claim 25, wherein said polypeptide is capable of dimerizing to form a soluble immunogenic dimer effective to induce said anti-self IgE response in said mammal.

30. The immunogenic polypeptide of claim 25, wherein said non-self IgE portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion.

31. The immunogenic polypeptide of claim 30, wherein said first region comprises at least a portion of an IgE CH2 domain.

32. The immunogenic polypeptide of claim 30, wherein said second region comprises at least a portion of an IgE CH4 domain.

33. An immunogenic polypeptide, comprising a self IgE portion and a non-self IgE portion, wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal, and wherein said self IgE portion consists essentially of an N-terminal portion of a CH3 domain of IgE.

34. The immunogenic polypeptide of claim 33, wherein said mammal is a human.

35. The immunogenic polypeptide of claim 34, wherein said non-self IgE portion comprises an IgE sequence present in a non-placental mammal.

36. The immunogenic polypeptide of claim 35, wherein said non-placental mammal is selected from the group consisting of opossum, platypus, koala, kangaroo, wallaby, and wombat.

37. The immunogenic polypeptide of claim 33, wherein said polypeptide is capable of dimerizing to form a soluble immunogenic dimer effective to induce said anti-self IgE response in said mammal.

38. The immunogenic polypeptide of claim 33, wherein said non-self IgE portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion.

39. The immunogenic polypeptide of claim 38, wherein said first region comprises at least a portion of an IgE CH2 domain.

40. The immunogenic polypeptide of claim 38, wherein said second region comprises at least a portion of an IgE CH4 domain.

41. An immunogenic polypeptide, comprising a self IgE portion and a non-self IgE portion, wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal, and wherein said non-self IgE portion comprises an IgE sequence present in a non-placental mammal.

42. The immunogenic polypeptide of claim 41, wherein said mammal is a human.

43. The immunogenic polypeptide of claim 41, wherein said non-placental mammal is selected from the group consisting of opossum, platypus, koala, kangaroo, wallaby, and wombat.

44. The immunogenic polypeptide of claim 41, wherein said polypeptide is capable of dimerizing to form a soluble immunogenic dimer effective to induce said anti-self IgE response in said mammal.

45. The immunogenic polypeptide of claim 41, wherein said non-self IgE portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion.

46. The immunogenic polypeptide of claim 45, wherein said first region comprises at least a portion of an IgE CH2 domain.

47. The immunogenic polypeptide of claim 45, wherein said second region comprises at least a portion of an IgE CH4 domain.

48. A polypeptide, comprising a self IgE portion and a non-self IgE portion, wherein said polypeptide lacks light chain Ig sequences and is effective to induce an anti-self IgE response in a mammal, wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE.

49. The polypeptide of claim 48, wherein said mammal is a human.

50. The polypeptide of claim 49, wherein said non-self IgE portion comprises an IgE sequence present in a non-placental mammal.

51. The polypeptide of claim 50, wherein said non-placental mammal is selected from the group consisting of opossum, platypus, koala, kangaroo, wallaby, and wombat.

52. The polypeptide of claim 48, wherein said non-self IgE portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion.

53. The polypeptide of claim 52, wherein said first region comprises at least a portion of an IgE CH2 domain.

54. The polypeptide of claim 52, wherein said second region comprises at least a portion of an IgE CH4 domain.--